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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
U 013528-7

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on October 3, 2006

Signature _____

Typed or printed name Janet I. Cord

Application Number	Filed
10/023,427	December 12, 2001

First Named Inventor: Harshal P. Bhagwatwar

Art Unit	Examiner
1618	Fubara, Blessing M.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 33778

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

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Telephone number

October 3, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF,Co mmissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: HARSHAL P. BHAGWATWAR, ET AL.

Serial No.: 10/023,427 Group No.: 1618

Filed: DECEMBER 12, 2001 Examiner: FUBURA, BLESSING M.

For: NOVEL *IN SITU* FORMING CONTROLLED RELEASE MICROCARRIER DELIVERY SYSTEM

Attorney Docket No.: U 013528-7

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Submission Accompanying Request for Pre-Appeal Brief Conference

This pre-appeal brief request for review is being filed because there is a clear legal or factual deficiency in the rejections.

The drug delivery system claimed in this application (claims 72-90, 93, 96 and 97 claim the drug delivery system *per se*; claims 91 and 92 claim a method for treating a health disorder, disease or medical condition using the claimed drug delivery system of the invention, and claim 94, which claims a method for prophylaxis of a health disorder–NOTE: claim 94 will be cancelled after the panel review is completed.), unlike the prior art formulations cited by the examiner, forms microparticles only on injection into the body or when contacted with an aqueous fluid. Careful reading of the application makes it clear that an aqueous phase is not present in the drug delivery system. This differs from other drug delivery systems that already have an aqueous phase in the product to be administered. In Phillips v. AWH Corp., 75 USPQ2d 1369 (Fed. Cir. 2005), the Federal Circuit noted that in analyzing the language of the claims, the court must also consider the specification to see

how the term in question is used there. The court noted that the specification is supposed to describe the invention. This being the case, one should be able to determine what a claim to that invention means by reading the specification.

As stated above, it is clear from the specification that an aqueous phase is not present in the drug delivery system and therefore, there is no legal or factual reason to require that the word "comprising" be replaced by "consisting of". This is supported by the following paragraphs of the specification (the first paragraph number being the paragraph number used in the original application and the second paragraph number (in parentheses) being the paragraph number in the published application US 20030049320):

[0001] ([0001])- According to this paragraph, the gelled composition comprises a polymer, an organic solvent, an oil and an emulsifier resulting in a ready-to-use, gelled, syringeable, solution-in-oil dispersion. There is no disclosure nor suggestion of an aqueous phase.

Paragraph [00012] ([0012-0015]) states that the current invention addresses the need for a ready-to-use, stable, gelled, polymeric dispersion, encompassing a uniformly distributed biologically active, bioinactive agent or mixture thereof which is capable of rapidly forming in-situ, polymeric microcarriers of a controlled size, distribution and shape upon coming in contact with an aqueous medium. This clearly supports that the claimed drug delivery system does not include an aqueous component. If the drug delivery system of the invention included an aqueous component, then the polymeric microcarriers would already be formed and there would be no need to have the drug delivery system come into contact with an aqueous

medium. This interpretation is supported by claim 72 which includes that the drug delivery system comprises non-preformed microparticles.

Further support for this interpretation is found in paragraph [0014] ([0016]) where it is stated that "On placing such a dispersion into a body where there is an aqueous component, a multitude of microcarriers is formed." Clearly, if there was an aqueous component in the claimed drug delivery system, the drug delivery system would not have to be put in contact with an aqueous component in order to form the microcarriers /microparticles.

Although it is stated in paragraph [00016] ([0018]) that water can be used as a solvent, this does not mean that an aqueous phase is present. This is evidenced by the remainder of the paragraph:

> Thus, for example, a solution of a polymer in DMSO when emulsified into a solution of the nonionic emulsifier (sorbitan monostearate, sorbitan monopalmitate or a mixture thereof) in the oil at an elevated temperature and subsequently cooled, provides a true polymer droplet-in-oil dispersion. This dispersion is a viscous gel at temperatures of 2-80^0 C. but flows upon application of shear through a syringe-needle assembly. **Upon coming in contact with an aqueous medium, discrete microcarriers are formed. The presence of the nonionic emulsifier of the invention in this novel dispersion allows the formation of a ready-to-use microcarrier-forming composition which causes rapid emulsification of the oil phase on contact with an aqueous medium.** (Emphasis added).

If there was an aqueous phase present in the drug delivery system, it would not be necessary to contact the claimed drug delivery system with an aqueous medium.

Other paragraphs of the specification that describe that the microcarriers are formed when the drug delivery system is contacted with an aqueous medium and are not formed sua sponte , include paragraphs [00018], ([0020]); [00033], ([0035]); [00034], ([0036]); [00036], ([0038]); and [00083], ([0089-0091]).

Based on the description discussed above, the Examiner has no legal basis to require that claim 72 be amended to replace "comprising" with "consisting of." It is noted that in each reference cited by the Examiner, an aqueous phase is disclosed specifically. See pages 4-11 of the Office Action of May 3, 2006.

If it would aid the panel of examiners, a sample of the delivery system can be provided to demonstrate that the delivery system is novel and non-obvious over prior art.